

# **United States Government Accountability Office Washington, DC 20548**

June 29, 2007

The Honorable Carl Levin Chairman The Honorable John McCain Ranking Member Committee on Armed Services United States Senate

The Honorable Ike Skelton Chairman The Honorable Duncan L. Hunter Ranking Member Committee on Armed Services House of Representatives

Subject: Military Health: DOD's Vaccine Healthcare Centers Network

Members of the military have long been required to receive immunizations. The Department of Defense (DOD) estimates that over 2.2 million servicemembers receive at least one mandatory immunization annually. Immunizations are provided through the administration of vaccines, which contain "antigens" or parts of a specific virus or bacterium that are used to trigger an immune response to protect the body from disease. DOD's immunization requirements vary depending on several factors, such as a servicemember's branch of military service, location, age, and type of personnel, such as newly enlisted recruits, those conducting high-risk travel, and reserve forces.

No immunization is completely safe. Like all individuals, servicemembers may experience side-effects as a result of their immunizations, known as adverse events. Most adverse events consist of relatively mild reactions, such as swelling near the site of the immunization. However, a small number of individuals may experience more severe reactions, such as some servicemembers who received the anthrax and smallpox vaccines. DOD made these vaccines mandatory starting in 1998 and 2002, respectively, out of concern that these pathogens could

<sup>1</sup>The military first mandated immunizations in 1777, when General George Washington required troops to receive the smallpox vaccine. Since then, the smallpox vaccine has been given to members of the military during major conflicts including the Civil War, World War I, World War II, the Korean War, and the Vietnam War. The smallpox immunization requirement was suspended in 1990 and was subsequently reinstated for certain personnel in 2002.

<sup>2</sup>For the purposes of this report, we use the term "servicemembers" to include all members of the military, including active duty, reserve, and National Guard servicemembers. In addition to servicemembers, DOD may require others to receive immunizations, such as DOD contractors and family members who accompany service members to military locations.

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Form Approved OMB No. 0704-0188 be used as biological weapons.<sup>3</sup> Some servicemembers who received these vaccines experienced severe reactions such as migraines, heart problems, and the onset of diseases including diabetes and multiple sclerosis. Since then, the adverse events associated with these vaccines have caused concern among members of Congress about the safety of some mandatory immunizations.

In response to three congressional directives, DOD established the Vaccine Healthcare Centers (VHC) Network in September 2001 with initial funding provided by the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC). The purpose of the VHC Network is to meet the health care needs of servicemembers receiving mandatory immunizations. This includes educating servicemembers about how to prevent adverse events and diagnosing and treating those with severe reactions. In September 2001, the National VHC—or headquarters—opened at Walter Reed Army Medical Center in Washington, D.C., along with a regional VHC site in the same location. By 2003, three more regional VHCs had opened at the Womack Army Medical Center at Fort Bragg in North Carolina, the Wilford Hall Medical Center at Lackland Air Force Base in Texas, and the Portsmouth Naval Medical Center in Virginia.

DOD placed the VHC Network under the command of the Army Surgeon General. However, neither DOD nor the Army provided the VHC Network with a mission statement. As a result, VHC Network officials defined their own mission. In addition, since 2001, the VHC Network—which is not included in DOD's long-term budget planning—has relied upon funding provided on an annual basis from a variety of sources. Its lack of both a recognized mission and a specified funding source caused uncertainty among VHC Network officials about its future existence and organizational structure. However, in December 2006, DOD made several decisions regarding the VHC Network. These decisions, which become effective in fiscal year 2008, address the VHC Network's funding and mission and transfer it to the command of the Military Vaccine Office (MILVAX), which oversees military immunization policies across DOD.

<sup>&</sup>lt;sup>3</sup>The military suspended the use of the anthrax vaccine in October 2004, in response to a court order that expressed concern regarding the administrative process by which the Food and Drug Administration (FDA) approved the vaccine for its use. The court subsequently modified this order, which allowed the military to begin to offer the anthrax vaccine on a voluntary basis in April 2005. In December of 2005, FDA determined that the vaccine protected against all routes of exposure to anthrax spores, including inhalation. In October 2006, after the court order had expired, DOD announced that it was resuming mandatory vaccination for certain personnel and issued a memorandum that designated which personnel would be required to receive the immunization and which servicemembers would be eligible to receive it on a voluntary basis.

<sup>&</sup>lt;sup>4</sup>The first directive was contained in the conference report accompanying the Consolidated Appropriations Act for Fiscal Year 2000. Congress directed the National Institutes of Health, CDC, and DOD to conduct a collaborative study on the safety and efficacy of vaccines used against biological agents. See H.R. Conf. Rep. 106-479, at 727 (1999). The second directive was contained in section 751 of the National Defense Authorization Act for Fiscal Year 2001. This provision required DOD to establish a system for monitoring adverse reactions to the anthrax vaccine and to establish guidelines under which servicemembers could obtain access to a treatment facility for expedited treatment and follow up of adverse events. See Pub. L. No. 106-398 App., § 751, 114 Stat. 1654, 1654A-193 (2000) (codified at 10 U.S.C. § 1110). The third directive called for the continued study of the anthrax vaccine by CDC and was provided in the Consolidated Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554 App., 114 Stat. 2763, 2763A-25 (2000). Congress indicated in a report accompanying the 2001 appropriation law that the establishment of the VHC Network would, among other things, facilitate data collection and training. See H.R. Conf. Rep. No. 106-1033, at 166 (2000).

Two recent laws—the National Defense Authorization Act for Fiscal Year 2006 and the National Defense Authorization Act for Fiscal Year 2007—contained provisions that required us to examine several issues related to the VHC Network.<sup>5</sup> In response, and after consultation with the committees of jurisdiction, this report describes (1) the efforts the VHC Network is undertaking to address the needs of servicemembers arising from mandatory military immunizations and (2) how DOD has supported the mission of the VHC Network.

To describe the efforts the VHC Network is undertaking to address the needs of servicemembers, 6 we interviewed officials from the National VHC, and from each of the four regional VHCs, on the VHC Network activities. We also interviewed DOD officials at the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Board, the DOD Center for Deployment Health Research, the Army Medical Research and Materiel Command, the Preventive Medicine Residency Training Program of the Uniformed Services University of the Health Sciences, and the Offices of the Surgeon General for the Army, Air Force, and Navy to obtain their perspectives on the mission and activities of the VHC Network. In addition, we interviewed officials from MILVAX to obtain information on immunization policies and related requirements and to understand its relationship with the VHC Network. We also interviewed two providers—one in the Army and another in the Air Force—who have treated servicemembers experiencing adverse events, and a Navy nurse familiar with immunizations. During our interviews, we also obtained information regarding the education and assistance the VHC Network offers military and civilian health care providers and the services that it provides to family members and others, such as DOD contractors, receiving immunizations. Finally, we spoke to CDC officials to understand how the role CDC plays in monitoring adverse events among the civilian population compares to the VHC Network's role in the military. We obtained and analyzed relevant documentation and data on the VHC Network's activities from the entities we contacted.

To determine how DOD has supported the mission of the VHC Network, we interviewed officials at the Assistant Secretary of Defense for Health Affairs, MILVAX, the Offices of the Surgeon General for the Army, Air Force, and Navy, and the VHC Network. We also obtained budgetary information concerning the VHC Network, including funding sources, from fiscal year 2001 through fiscal year 2006. In addition, we reviewed VHC Network staffing levels during April 2007. We supplemented this work with interviews with CDC officials to obtain information on the funding CDC provided to help launch the VHC Network in 2001. To assess the reliability of the VHC Network's information on regional staffing, clinical support mechanisms, and educational resources, we talked with agency officials about their data collection and quality control procedures and reviewed relevant documentation. We determined that the data were sufficiently reliable for the purposes of this report. We performed our work from June 2006 through May 2007, in accordance with generally accepted government auditing standards.

<sup>&</sup>lt;sup>5</sup>See Pub. L. No. 109-163, § 736, 119 Stat. 3136, 3356 and Pub. L. No. 109-364, § 737(a), 120 Stat. 2083, 2302 (2006).

<sup>&</sup>lt;sup>6</sup>We consider the efforts of the VHC Network to address the needs of those receiving the anthrax immunization under both mandatory and voluntary circumstances to be within the scope of this report.

#### **Results in Brief**

The VHC Network supports the health care needs of servicemembers that may arise from military immunizations in three ways. First, it offers clinical support. For example, it provides clinical care to servicemembers experiencing potential adverse events, and, in cases where the patient is not located near a regional VHC site, it may remotely coordinate the patient's care with the other providers directly involved in the patient's treatment. Second, the VHC Network conducts research to improve the safe administration of vaccines and the prevention, identification, and treatment of adverse events. Third, it educates servicemembers and military health care staff on adverse events. For example, the VHC Network makes information available by conducting briefings and posting training materials on a Web site. In general, DOD and CDC officials said that they consider the VHC Network's contributions important, particularly in the area of clinical care. However, several DOD officials, including DOD medical staff members, added that its educational efforts may not be reaching enough military health care providers who remain unaware, for example, of some adverse events and the role of the VHC Network.

DOD's December 2006 decisions, including the plan to place the VHC Network under the command of MILVAX, will give the VHC Network recognition as a formal entity within DOD's command structure and an established mission within DOD, and have the potential to provide access to a more stable source of funding, when they are implemented in fiscal year 2008. According to VHC Network officials, the absence of such a mission and a place in DOD's long-range budget has made it difficult to plan strategically, develop and maintain regional VHC sites, and attract and retain staff. Under DOD's new plan, the Army, Air Force, and Navy will each provide funding for the VHC Network. In addition, there will be opportunities for all the services to provide input into decisions regarding the activities of the VHC Network. VHC Network officials stated that they hope that DOD's decisions will provide opportunities for the VHC Network to plan for and accomplish its mission with greater predictability.

We provided a draft of this report to DOD and HHS. We received written comments from DOD stating that it concurred with our findings. HHS provided technical comments, which we incorporated as appropriate.

#### **Background**

The human body generally tolerates immunizations without significant side effects and most immunized individuals require no treatment. Reactions at or near the injection site, such as redness, itching, and swelling, are not unusual among those experiencing adverse events. Less common reactions are systemic events that affect the entire body, such as fever, chills, or nausea. Instances of severe adverse events are rare. Officials from the VHC Network and CDC estimate that between 1 and 2 percent of immunized individuals may experience severe adverse events, which could result in disability or death. Some of these events may occur coincidentally following immunization, while others may truly be caused by immunization. The fact that an adverse event occurred following immunization is not conclusive evidence that the event was caused by a vaccine. A comprehensive evaluation of the patient's

condition may be necessary to make this determination, and may be followed by treatment or exemption<sup>7</sup> from further doses of a vaccine.<sup>8</sup>

The VHC Network is currently overseen by the Army's North Atlantic Regional Medical Command (NARMC), which operates under the Army Surgeon General. As of April 2007, the VHC Network had 40 staff. Fourteen of them work for the National VHC in medical, educational, and administrative capacities. The remaining 26 staff members worked for the regional VHCs (see table 1).

Table 1: Regional VHC Staff Distribution, as of April 2007						
	Walter Reed VHC	Fort Bragg VHC	Portsmouth VHC	Wilford Hall VHC	Total	
Medical personnel	4	3	3	4	14	
Support staff	5	3	2	2	12	
Total	9	6	5	6	26	

Source: The VHC Network.

Note: Medical personnel include the medical director, nurse practitioners, and health educators. Support staff include the patient service coordinator and other administrative support.

The Office of the Secretary of Defense designated the Army as the executive agent for the DOD-wide military immunization program. The Army, through the Office of the Army Surgeon General, established MILVAX to coordinate efforts in immunization services for all DOD components. Describing MILVAX is charged with delivering education, enhancing scientific understanding, promoting quality, and helping to develop and coordinate military immunization programs for all DOD services worldwide. For example, MILVAX provides information related to military immunization requirements through such vehicles as Immunization University, an online source of guidelines and training materials for those administering military immunizations. In addition, MILVAX monitors databases maintained by each of the military services that track the administration of vaccines and health of servicemembers before and after immunization to identify patterns in symptoms that might indicate adverse events. MILVAX is also responsible for ensuring adherence to standards applicable to the proper shipping and handling of some temperature-sensitive immunization products.

<sup>&</sup>lt;sup>7</sup>Under current DOD-wide policy, servicemembers may receive a temporary (lasting up to 365 days) or permanent medical exemption from immunizations from appropriate medical personnel, based on factors such as preexisting immunity, severe reactions to prior vaccination, or pregnancy, and still be considered medically ready for deployment.

<sup>&</sup>lt;sup>8</sup>For some vaccines, such as the anthrax immunization, immunity is achieved after the administration of multiple doses of vaccine.

<sup>&</sup>lt;sup>9</sup>An executive agent in DOD provides defined levels of support for operational missions or other activities that provide support to two or more DOD services. According to DOD Directive 5101.1, an executive agent is the head of a DOD component to whom the Secretary or Deputy Secretary of Defense has assigned specific responsibilities, functions, and authorities. There are 10 medical programs operating under executive agents in DOD; the Army is the executive agent for 9 of those programs.

<sup>&</sup>lt;sup>10</sup>Programs, such as MILVAX, that operate under an executive agent have separate and identifiable lines in DOD's internal budget process.

In January 2006, DOD required that, at a minimum, more than 75 percent of servicemembers must be rated as "fully medically ready." To meet this requirement, among other things, servicemembers must receive all immunizations that, depending on their particular circumstances, are required of them. Most immunizations involve injections, and some require multiple doses. Table 2 shows vaccines generally required for servicemembers.

Population segment	Vaccine
Trainees	Diphtheria, hepatitis A, hepatitis B, influenza, measles, meningococcal disease, mumps, pertussis, poliovirus, rubella, tetanus, varicella, yellow fever
Routine during career (both active duty and reserves)	Diphtheria, hepatitis A, influenza, pertussis, tetanus
Individualized based on deployment or travel to high-risk areas	Anthrax, hepatitis B, Japanese encephalitis, meningococcal disease, smallpox, typhoid, yellow fever
Individualized based on occupational or personal needs	Haemophilus influenzae type b, hepatitis B, meningococcal disease, pneumococcal disease, rabies, varicella

Source: DOD.

Note: Immunization policy varies among military services, based on individual needs.

# The VHC Network Provides Clinical Support, Performs Research, and Offers Education to Address Servicemembers' Needs

The VHC Network undertakes a variety of activities to support the needs of servicemembers who receive immunizations. We have grouped these activities into three categories—clinical support, research, and education. By focusing on these activities, the VHC Network attempts to prevent, identify, and treat adverse events.

#### The VHC Network Offers Clinical Support

The VHC Network offers clinical support to servicemembers, health care providers, and others, such as family members. Such support is available in person to servicemembers and others who visit the VHC Network's regional locations. Clinical support is also provided by telephone—servicemembers, and others with clinical questions, may call the DOD Vaccine Clinical Call Center, which is operated by the VHC Network. This center is available 24 hours a day, 7 days a week. According to its officials, the VHC Network has responded to at least 1,700 calls made to its call center, from June 2004—when the call center first became operational—through March 2007. The VHC Network also provides clinical support through its Web site, which contains a link that allows for confidential e-mail communication. Through this link, according to VHC Network officials, 146 inquiries have been addressed

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<sup>&</sup>lt;sup>11</sup>Medical readiness requires that service members are fit and ready to deploy. For example, active service members are required to have an annual dental examination, pass an annual health assessment, and be tested for human immunodeficiency virus within the previous 24 months, in addition to receiving their mandatory immunizations.

from August 2005, when the link became operational, through March 2007. Through these venues, the VHC Network provides the following clinical support.

Providing clinical care: The VHC Network treats servicemembers experiencing potential adverse events, particularly in instances where symptoms have been persistent, nonresponsive to previous treatment, and debilitating. VHC Network physicians may serve as primary care providers, providing in-person care, for patients at the regional VHCs. For patients at other locations, the VHC Network may serve as the long-distance case manager. In such cases, VHC Network physicians use telemedicine to remotely coordinate a patient's care with their primary care providers, by telephone or through the Internet. Regardless of whether patient care is provided directly or remotely, it may include diagnostic assessments, such as performing physical examinations, evaluating the results of laboratory tests, consulting with current and past healthcare providers, conducting comprehensive interviews regarding past health history with patients and family members, and providing necessary treatment. Depending on the patient's needs, the VHC Network may also make referrals to other health care providers for subspecialty care, and engage in long-term follow-up of the patient's progress. According to VHC Network officials, from September 2001, when the VHC Network was created, through mid-April 2007, the VHC Network has provided clinical treatment to about 2,400 servicemembers.

Responding to immunization-related questions: The VHC Network staff answer questions from servicemembers and their families, providers, and others. The questions may be general or unique to a patient's individual situation, and involve topics such as the following:

- Safe administration of vaccines to prevent adverse events: For example, should servicemembers be immunized if they have a history of certain allergies or when they are taking a specific prescription medication?
- Identification of potential adverse events: For example, could symptoms of vertigo, or short-term memory loss be related to a recent immunization?
- Safe practices after immunization: For example, are there precautions a servicemember should take after receiving certain vaccines, such as the smallpox vaccine, where there is a risk that the virus from the vaccination site may be transferred and infect family members or others with whom the servicemember has close contact?

Providing clinical input to administrative decisions: Because of its clinical expertise in adverse events following immunization, the VHC Network provides input in certain administrative decisions involving the longer-term health care needs of those who have experienced adverse events as a result of mandatory immunizations. For example, it assists servicemembers in obtaining medical exemptions from further immunizations, to avoid future severe reactions. In other situations, it supports patients who are no longer on active duty in obtaining military health care benefits so they may be treated for symptoms associated with adverse events. For example, it

<sup>&</sup>lt;sup>12</sup>In addition, according to VHC Network officials, the VHC Network has also responded to e-mails outside of the secure link.

helps members of the reserves with establishing their eligibility for military health care benefits by providing documentation on the link between their symptoms and the mandatory immunizations they received while on active duty.<sup>13</sup>

Many of the DOD officials, military health care staff, and CDC officials we interviewed considered the VHC Network's clinical support efforts both important and unique. For example, several indicated that the VHC Network is uniquely positioned in the military to care for those experiencing adverse events, because of the staff's expertise in immunology and their continuous exposure to and familiarity with such cases. <sup>14</sup> In addition, MILVAX officials told us that the VHC Network's regional sites provide a single point of access to coordinated medical care for servicemembers experiencing adverse events. As a result, these officials told us that servicemembers benefit greatly because they do not have to go through a lengthy process of seeing several providers before being diagnosed and treated.

### The VHC Network Conducts Research to Improve Vaccine Safety

The VHC Network conducts research to improve DOD's ability to identify, treat, and prevent adverse events related to immunizations. The VHC Network uses information it gathers through its clinical support activities and supplements that information with medical literature reviews and joint efforts with other entities with an interest in military immunizations. For example, the VHC Network regularly coordinates with MILVAX in researching possible adverse events and related trends. Through its routine review of military immunization databases, MILVAX may identify a trend in certain symptoms and ask the VHC Network to investigate the cause. The two entities may also collaborate in their research activities, such as a recent study of the flu vaccine that compared the safety of the injectable vaccine to that of the nasal spray vaccine. The VHC Network also engages in research projects with other entities such as CDC and universities, covering topics such as immunologic responses to anthrax immunization and postimmunization chronic fatigue syndrome. Through these research efforts, the VHC Network aims to improve vaccine safety by the following:

<u>Safely administering vaccines</u>: As a result of its research on possible causes of adverse events, the VHC Network created a screening form to capture servicemembers' health histories, prior to immunization. Health care staff administering vaccines may use these forms to identify any potential vaccine-related risks. As a result of the information provided, they may give the servicemember a different vaccine dosage than others receive or a medical exemption from the vaccine.

<u>Identifying and treating potential adverse events</u>: According to VHC Network officials, the VHC Network, through its clinical experience and related evaluation and research work, facilitates the discovery of new vaccine-related adverse events, particularly rare ones, which may not be as readily identified by database research and analysis. For example, VHC Network officials told us that they determined that inflammation of the

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<sup>&</sup>lt;sup>13</sup>Most members of the reserves are not enrolled in a military health care insurance program when they are not on active duty. However, they may be eligible for military health care benefits or health care provided by the Department of Veterans Affairs, for service-related injuries or illness incurred or aggravated while on active duty.

<sup>&</sup>lt;sup>14</sup>Providers at the regional VHCs are civilians and do not rotate among facilities.

heart may be caused by the smallpox vaccine and that they disseminated that information throughout the military medical community through presentations, the VHC Network's Web site, and other means. Without this information, the chest pains some servicemembers experience may not be associated by providers with the immunization and instead may be misdiagnosed as a different heart ailment. In addition, the VHC Network provides tools on its and MILVAX's Web sites to further assist military providers in properly diagnosing and treating adverse events. For example, the VHC Network has created clinical definitions for six additional adverse events not previously characterized, such as new onset of headaches, muscle pain, chronic fatigue, and autoimmune disorders, in order to help providers identify such symptoms as possible adverse events. In addition, the VHC Network provides clinical guidelines to further assist providers in their diagnosis and care of adverse events.

Many officials at MILVAX, other DOD entities with an interest in military health care research, and CDC told us that they believe that the VHC Network has made important contributions to research. For example, MILVAX officials cited the VHC Network's role in the investigation of the causes of death of three servicemembers after receiving multiple immunizations, including the smallpox vaccine, the VHC Network's study of the possible genetic predisposition to adverse events, and its work on the association between inflammation of the heart and the smallpox vaccine.

The VHC Network Educates Servicemembers, Providers, and Others about Adverse Events and VHC Resources

The VHC Network has a number of activities to educate servicemembers, providers, and other military health care staff about adverse events, the role of the VHC Network, and the resources it provides. The VHC Network uses a variety of approaches, including the following:

<u>Presentations</u>: The VHC Network staff make various presentations about vaccine-related adverse events and the role of the VHC Network. The VHC Network estimates that in 2006 it conducted 810 presentations. For example, VHC Network staff conducted briefings at the Soldier Readiness Processing program, which prepares servicemembers for deployment, at the four VHC locations. These briefings accounted for almost 30 percent of all presentations and reached about 20,000 servicemembers. Other presentations involved briefings at mass immunization sites, family support group meetings, and various orientation sessions, for example, for new hospital staff at military medical centers including the four VHC sites. VHC Network staff also participated in health fairs and conferences.

<u>Printed material</u>: The VHC Network publishes the Immunization Tool Kit, a booklet that contains vaccine-related information on matters such as the safe administration of immunizations, possible adverse events, and sources of additional information targeted to military and civilian health care providers. Almost 78,800 copies of the Immunization Tool Kit have been distributed since it was first published in 2001, through March 2007.

<u>Web resources</u>: The VHC Network offers educational resources on its Web site such as Project Immune Readiness, a distance learning tool that targets military health care staff administering immunizations, but is also available to anyone interested in learning more about vaccines. Among other things, the tool uses educational modules to teach health care staff how to prevent and recognize adverse events. For example, in 2005, 2,060 people completed 7,779 of these modules.

<u>Collaborative efforts</u>: The VHC Network and MILVAX regularly collaborate in education efforts. For example, MILVAX reviews new material to be included in the VHC Network's Project Immune Readiness, such as guidance on the proper handling and storage of vaccines. In addition, a representative of the Uniformed Services University of the Health Sciences, which provides training on public health in the military, told us that VHC Network staff have assisted in developing its preventive medicine training.

While many DOD officials and medical staff we contacted acknowledged the contributions of the VHC Network in education, several said that they do not believe that enough military healthcare providers are being reached. Specifically, we were told that many providers are still unaware of the VHC Network, its role, and the potential links between certain symptoms and adverse events, which, in turn, affects their ability to not only provide proper diagnosis and treatment, but also to educate those being immunized. <sup>15</sup> According to DOD officials with whom we spoke, the nature of DOD's organization, with its continuous rotation and restructuring of personnel, creates a challenge for the VHC Network to effectively reach out to every targeted audience.

# Recent Decisions by DOD Have the Potential to Provide Greater Stability to the VHC Network

In December 2006, DOD made decisions addressing matters regarding the VHC Network, including its organizational status, mission, and funding. VHC Network officials stated that the unpredictability of the VHC Network's budget from one year to the next had affected facility development and staff retention, and compromised the VHC Network's ability to provide services and to accomplish its mission. DOD's recent decision to place the VHC Network under the command of MILVAX, beginning in fiscal year 2008, provides recognition of the VHC Network's status and mission, in addition to offering the potential for more funding security through access to DOD's long-term budget planning process.

<u>Uncertainties in DOD's Commitment to the VHC Network Had Affected Its Status, Mission, and Funding</u>

Since its establishment in 2001, the VHC Network had been operating under the command of the Army. Although the VHC Network officials defined their own mission, they did not undertake the steps necessary to establish a recognized mission within DOD. The VHC Network also sought, but never obtained, the oversight of a DOD executive agent, which

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<sup>&</sup>lt;sup>15</sup>For example, according to CDC's Morbidity and Mortality Weekly Report of May 18, 2007, a child of a servicemember who received the smallpox vaccine experienced a life-threatening reaction to his father's immunization. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5619a4.htm, downloaded on May 18, 2007.) Such a reaction can occur from close physical contact with people who have recently received this vaccine. Greater awareness of adverse events and their prevention among servicemembers and military health care staff could help prevent such incidents.

would have provided it with a defined mission within the agency. In addition, the structural and financial support for the VHC Network was not formalized. Although the VHC Network was initially designed to serve the Army, Air Force, and Navy, officials from the Air Force and Navy told us that they did not contribute to formulating the mission and activities of the VHC Network regional sites located at their bases and, consequently, they had little incentive to financially support the VHC Network's activities and mission.

The VHC Network had not been included in the military's long-term budget planning, which, VHC Network officials stated, limited their ability to strategically plan to accomplish their mission. VHC Network budget requests were submitted to the Army annually beginning in fiscal year 2002; however, the VHC Network was never incorporated into the Army's budget. Similarly, although requests were submitted for inclusion in DOD's 5-year budgets, <sup>16</sup> prepared in fiscal years 2004 and 2006, the VHC Network's costs were not included in the 5-year budgets.

The VHC Network obtained funding from a variety of sources, relying primarily on funds provided by the Army Surgeon General on a year-by-year basis from fiscal year 2002 through fiscal year 2006. During this period, the Army Surgeon General provided the VHC Network approximately \$21.1 million from its allocated Global War on Terrorism (GWOT) funds. In addition, for fiscal years 2005 and 2006, NARMC provided approximately \$177,000 to support VHC Network activities not covered by GWOT funds. About \$5.5 million from the Defense Health Program appropriation was directed to be spent on the VHC Network, as outlined in conference agreements for fiscal years 2003 and 2006. For fiscal years 2003 through 2006, MILVAX provided funding for activities such as VHC Network educational efforts and the operation of the DOD Vaccine Clinical Call Center. Table 3 shows the VHC Network's sources of funding for fiscal years 2002–2006.

<sup>&</sup>lt;sup>16</sup>The Five-Year Defense Program budget is prepared on a biannual basis, 2 years in advance of the 5-year period and is meant for long-range DOD planning.

<sup>&</sup>lt;sup>17</sup>GWOT funds support military operations to combat terrorism worldwide. Congress has been appropriating GWOT funds since 2001, through both annual appropriations and supplemental appropriations. Each service allocates its share of GWOT funds among its various functions. Only the Army has used GWOT funds to support the VHC Network.

<sup>&</sup>lt;sup>18</sup>The conference reports accompanying DOD's Appropriations Acts for Fiscal Years 2003 and 2006 contained funding tables indicating that a total of about \$5.5 million was to be spent on the VHC Network for those years. See H.R. Conf. Rep. No. 107-732, at 323 (2002) (accompanying Pub. L. No. 107-248) and H.R. Conf. Rep. No. 109-359, at 454 (2005) (accompanying Pub. L. No. 109-148).

Table 3: Funding Sources for VHC Network Activities, Fiscal Years 2002-2006 **Financial support** Fiscal year Fiscal year Fiscal year Fiscal year (dollars in millions) 2002 2003 2004 2005 2006 **Total** GWOT—Army Surgeon General \$5.200 \$1.920 \$5.640 \$5.551 \$2.874 \$21.185 **NARMC** 0.117 0.060 0.177 Defense Health Program Appropriations<sup>a</sup> 2.543 2.970 5.513 **MILVAX** 0.444 0.623 0.610 0.366 2.043 **Total** \$5.200 \$6.278 \$6.270 \$28.918 \$4.907 \$6.263

Source: DOD.

Notes: Since February 2006, the VHC Network also received over \$2.3 million in grants and awards from DOD and the National Institutes of Health for various projects. The Army, Air Force, and Navy have also provided facility space and utilities for the VHC regional sites located at their bases.

<sup>a</sup>The conference reports accompanying DOD's Appropriations Acts for Fiscal Years 2003 and 2006 contained funding tables indicating that a total of about \$5.5 million was to be spent on the VHC Network for those years. See H.R. Conf. Rep. No. 107-732, at 323 (2002) (accompanying Pub. L. No. 107-248) and H.R. Conf. Rep. No. 109-359, at 454 (2005) (accompanying Pub. L. No. 109-148).

Although the total annual funding for the VHC Network has been fairly consistent from year to year, <sup>19</sup> according to VHC Network officials, its exclusion from the Army's and DOD's budget projections complicated their ability to plan to provide services. For example, using fiscal year 2003 funds, the VHC Network built a regional site in Landstuhl, Germany. <sup>20</sup> The facility, costing approximately \$500,000, was completed in 2004. However, it was never occupied as a VHC regional site because the Army's 5-year budget projections for fiscal years 2006 to 2011 did not include funds to operate it. In addition, the Army wanted to clarify the mission of the VHC Network before it agreed to the VHC Network's expansion. The Army used the facility for other purposes.

In addition, VHC Network officials stated that the lack of reliable funding made it difficult to plan for staffing. For example, although Air Force and Navy personnel were utilizing services provided by the Wilford Hall and Portsmouth regional VHC sites, the Army considered closing these two regional VHCs in 2006, because of the absence of budgetary support from the Air Force and Navy. In particular, VHC Network officials noted that the uncertainty surrounding the future of the Portsmouth regional VHC made it difficult to recruit and retain staff there. The position of medical director at the Portsmouth site had been vacant since April 2004, when the site's last medical director resigned, citing funding uncertainty as part of her reason for resigning. By December 2006, when DOD made decisions addressing the mission and funding of the VHC Network, the Portsmouth VHC had been unable to recruit replacements for vacant staff positions, in part, because it could not ensure that the positions would exist in the upcoming year.

<sup>&</sup>lt;sup>19</sup>The VHC Network's fiscal year 2007 budget of \$6.105 million is funded through contributions from each of the services: the Air Force and Navy provided approximately \$1.6 million each, the Army provided approximately \$2.5 million, and the balance—approximately \$0.3 million—will be available through NARMC's GWOT allocations.

<sup>&</sup>lt;sup>20</sup>Landstuhl Regional Medical Center in Germany is the primary medical treatment center for casualties of U.S. operations within Europe, Southwest Asia, and the Middle East.

<sup>&</sup>lt;sup>21</sup>The Wilford Hall medical director currently serves as the Portsmouth medical director.

# <u>DOD's Decisions Could Make the VHC Network's Status, Mission, and Funding More Predictable</u>

DOD addressed the challenges facing the VHC Network in December 2006. After deliberations and unanimous agreement from the Army, Air Force, and Navy, DOD finalized decisions that will take effect in fiscal year 2008 regarding the VHC Network's mission, status, and funding. DOD's decisions provided recognition of the VHC Network's mission and place within DOD's command structure, and have the potential to provide access to more predictable funding. Its decisions included (1) placing the VHC Network under the command of MILVAX, (2) funding the VHC Network through contributions from each of the services, (3) formalizing Army, Air Force, and Navy input into and oversight of the VHC Network's mission and activities, and (4) providing outcomes oversight through an independent panel and a program review scheduled for 2010.

DOD provided the VHC Network clear organizational status through the decision to transfer it from NARMC's command to MILVAX. This will enable the VHC Network to share in the benefits afforded to MILVAX as a program operating under an executive agent. In addition, DOD concluded that all three services will periodically be asked to provide input into decisions concerning the VHC Network's activities, making each service a stakeholder in the success of the VHC Network's mission.

DOD also made several decisions that support the VHC Network's mission. For example, it concluded that the mission developed by the VHC Network was appropriate and that the VHC Network should continue with its current activities, including maintaining its network structure of a headquarters and regional sites. MILVAX and VHC Network officials are currently working together, with input from the services, to revise MILVAX's mission to include VHC Network activities. In addition, DOD decided that it would provide oversight of the VHC Network through an independent expert panel, which will conduct a program review in 2010. A MILVAX official stated that being within the MILVAX command may also provide the VHC Network additional opportunities to accomplish its mission. For example, MILVAX has a staff of 18 analysts in the United States and abroad who could assist in publicizing the VHC Network's services to clinicians and other military personnel. This official suggested that greater visibility may help ensure that those in need of the VHC Network's services know how to access them, which may be especially important considering the reintroduction of the mandatory anthrax immunization and DOD's January 2006 directive to achieve a higher level of medical readiness, partly through immunizing servicemembers.

DOD also took several actions to address the VHC Network funding concerns. While DOD's decision to place the VHC Network under MILVAX does not guarantee funding for the VHC Network, MILVAX's position as a program operating under an executive agent ensures that the VHC Network will be included in budget planning. With MILVAX's new responsibility for the VHC Network's mission and activities, the VHC Network's budget will be included within MILVAX's request for inclusion in DOD's 5-year internal budget projections, beginning with fiscal year 2008. In addition, DOD decided that the Army, Air Force, and Navy will share responsibility for funding the VHC Network. VHC Network officials told us that they hope that the changes in funding will provide the VHC Network with additional security and facilitate VHC Network officials' ability to plan activities.

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<sup>&</sup>lt;sup>22</sup>The National Defense Authorization Act for Fiscal Year 2007 prohibited DOD from downsizing or restructuring the VHC Network during fiscal year 2007. See Pub. L. No. 109-364, § 737(b), 120 Stat. 2083, 2302-03 (2006).

### **Agency Comments**

We provided a draft of this report to DOD and HHS. In its written comments, DOD said that it concurred with our findings. DOD's written comments are reprinted in enclosure I. HHS provided technical comments, which we incorporated as appropriate.

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We are sending copies of this report to the Secretary of Defense and other interested parties. In addition, this report will be available at no charge on GAO's Web site at <a href="http://www.gao.gov">http://www.gao.gov</a>. We will also make copies available to others upon request. If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure II.

Marcia Crosse

Director, Health Care

Enclosures – 2

### **Comments from the Department of Defense**



#### THE ASSISTANT SECRETARY OF DEFENSE

#### 1200 DEFENSE PENTAGON WASHINGTON, DC 20301-1200

JUN 1 4 2007

Ms. Marcia Crosse Director, Health Care U.S. Government Accountability Office 441 G Street, N.W. Washington, DC 20548

Dear Ms. Crosse:

This is the Department of Defense (DoD) response to the GAO draft report, GAO-07-787R, 'Military Health: DoD's Vaccine Healthcare Centers Network,' dated May 22, 2007 (GAO Code 290549).

Thank you for the opportunity to review the Draft Report and provide comments. I concur with the report's findings and results.

My points of contact on this audit are Dr. Michael Kilpatrick (Functional) at (703) 578-2675 and Mr. Gunther Zimmerman (Audit Liaison) at (703) 681-3492.

Sincerely,

S. Ward Casscells, MD

## **GAO Contact and Staff Acknowledgments**

### **GAO Contact**

Marcia Crosse at (202) 512-7114 or crossem@gao.gov

## Acknowledgments

Geraldine Redican-Bigott, Assistant Director; Adrienne Griffin; TaNaisha Lee; Pauline Seretakis; and Margaret Weber made key contributions to this report.

(290549)

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